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Weers

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(54) **LIPID-BASED COMPOSITIONS OF ANTIINFECTIVES FOR TREATING PULMONARY INFECTIONS AND METHODS OF USE THEREOF**

(71) Applicant: **Insmmed Incorporated**, Bridgewater, NJ (US)

(72) Inventor: **Jeff Weers**, Belmont, CA (US)

(73) Assignee: **INSMED INCORPORATED**, Bridgewater, NJ (US)

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(58) **Field of Classification Search**

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,091,572 A	5/1963	Luedemann et al.
3,136,704 A	6/1964	Charney
4,235,871 A	11/1980	Papahadjopoulos et al.
4,372,949 A	2/1983	Kodama et al.
4,394,448 A	7/1983	Szoka, Jr. et al.
4,396,630 A	8/1983	Riedl et al.
4,451,447 A	5/1984	Kaplan et al.
4,515,736 A	5/1985	Deamer
4,522,803 A	6/1985	Lenk et al.
4,547,490 A	10/1985	Ecanow et al.
4,588,578 A	5/1986	Fountain et al.
4,606,939 A	8/1986	Frank et al.
4,684,625 A	8/1987	Eppstein et al.
4,693,999 A	9/1987	Axelsson et al.
4,721,612 A	1/1988	Janoff et al.
4,767,874 A	8/1988	Shima et al.
4,833,134 A	5/1989	Kishimoto et al.
4,857,311 A	8/1989	Domb et al.
4,895,452 A	1/1990	Yiournas et al.
4,895,719 A	1/1990	Radhakrishnan et al.
4,897,384 A	1/1990	Janoff et al.
4,933,121 A	6/1990	Law et al.
4,952,405 A *	8/1990	Yau-Young A61K 9/127

424/423

4,963,367 A 10/1990 Ecanow

(Continued)

FOREIGN PATENT DOCUMENTS

CA	2174803 A1	10/1997
CA	2101241 C	12/1998

(Continued)

OTHER PUBLICATIONS

Webb et al. (Antimicrobial Agents and Chemotherapy, Jan. 1998; 42(1): 45-52).*

Office Action for U.S. Appl. No. 12/598,830, mailed Mar. 7, 2012, 5 pages.

Office Action for U.S. Appl. No. 12/598,830, mailed Oct. 23, 2012, 7 pages.

Office Action for U.S. Appl. No. 12/598,830, mailed Apr. 18, 2014, 5 pages.

(Continued)

Primary Examiner — Scott Long

(74) Attorney, Agent, or Firm — Cooley LLP

(57)

ABSTRACT

A system for treating or providing prophylaxis against a pulmonary infection is disclosed comprising: a) a pharmaceutical formulation comprising a mixture of free antiinfective and antiinfective encapsulated in a lipid-based composition, and b) an inhalation delivery device. A method for providing prophylaxis against a pulmonary infection in a patient and a method of reducing the loss of antiinfective encapsulated in a lipid-based composition upon nebulization comprising administering an aerosolized pharmaceutical formulation comprising a mixture of free antiinfective and antiinfective encapsulated in a lipid-based composition is also disclosed.